

CDRH Strategic Plan

Mission

**Current
Status**

Vision

**Strategic
Goals**

TPLC

ME

KM

MM

Next Steps

A Roadmap For Today's Briefing

- Our mission
- Current status
 - What do we do well ?
 - Where are we making progress?
 - Where are we falling behind ?
 - What are our new challenges ?
- Our vision
- Four strategic goals for getting there
- Next steps

The CDRH Strategic Vision

What you are **NOT** going to see today...

- a done deal
- reorganization plans
- an implementation plan
- a promise to do more with less
- a decreased commitment to review time performance

The CDRH Strategic Vision

What you are going to see is a work in-progress that...

- asks *what* we should be doing, not just what to do better;
- applies whether we are rich or poor;
- invests in our people for future strength; and
- calls on the Center's leadership to take an active role in preparing CDRH to meet the challenges of the future.

Center for Devices and Radiological Health

Mission:

CDRH promotes and protects the health of the public by ensuring the safety and effectiveness of medical devices and the safety of radiological products.

Current Status

Where do we stand in fulfilling our Mission ?

- What do we do well ?
- Where are we making progress?
- Where are we falling behind ?
- What are our new challenges ?

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Next Steps

CDRH: What do we do well?

- Premarket Program
 - 510(k), PMA, Supplements, Meetings, Guidance
- Mammography Program
- Reengineering
- Grass Roots Efforts
- CDRH's Web Sites

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Where are we making progress?

- Industry communication
- Standards development
- FDAMA implementation
 - dispute resolution
 - least burdensome
- Leveraging
- Harmonization

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CDRH: Where are we falling behind?

- Radiological health program
- Post marketing programs
- Science base
- Training and outreach
- Computer infrastructure
- Enforcement
- Device inspection coverage

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Next Steps

What new challenges do we face?

- Rapidly changing technology
- Global manufacturing
- Changing medical needs of an aging population
- Reuse
- Unregulated genetic tests
- MedSun and Medical errors
- Internet Abuse
- Tissue Engineering

So Much for Where We Stand

What's Our Vision for the Future?

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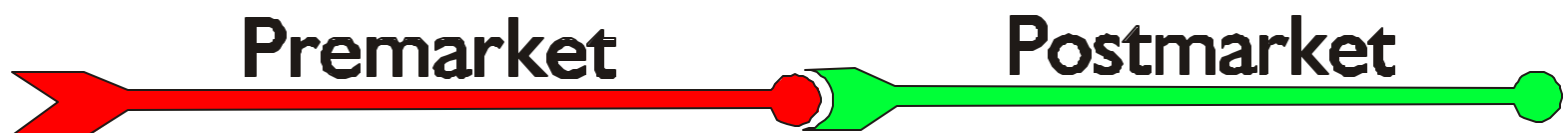
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Next Steps

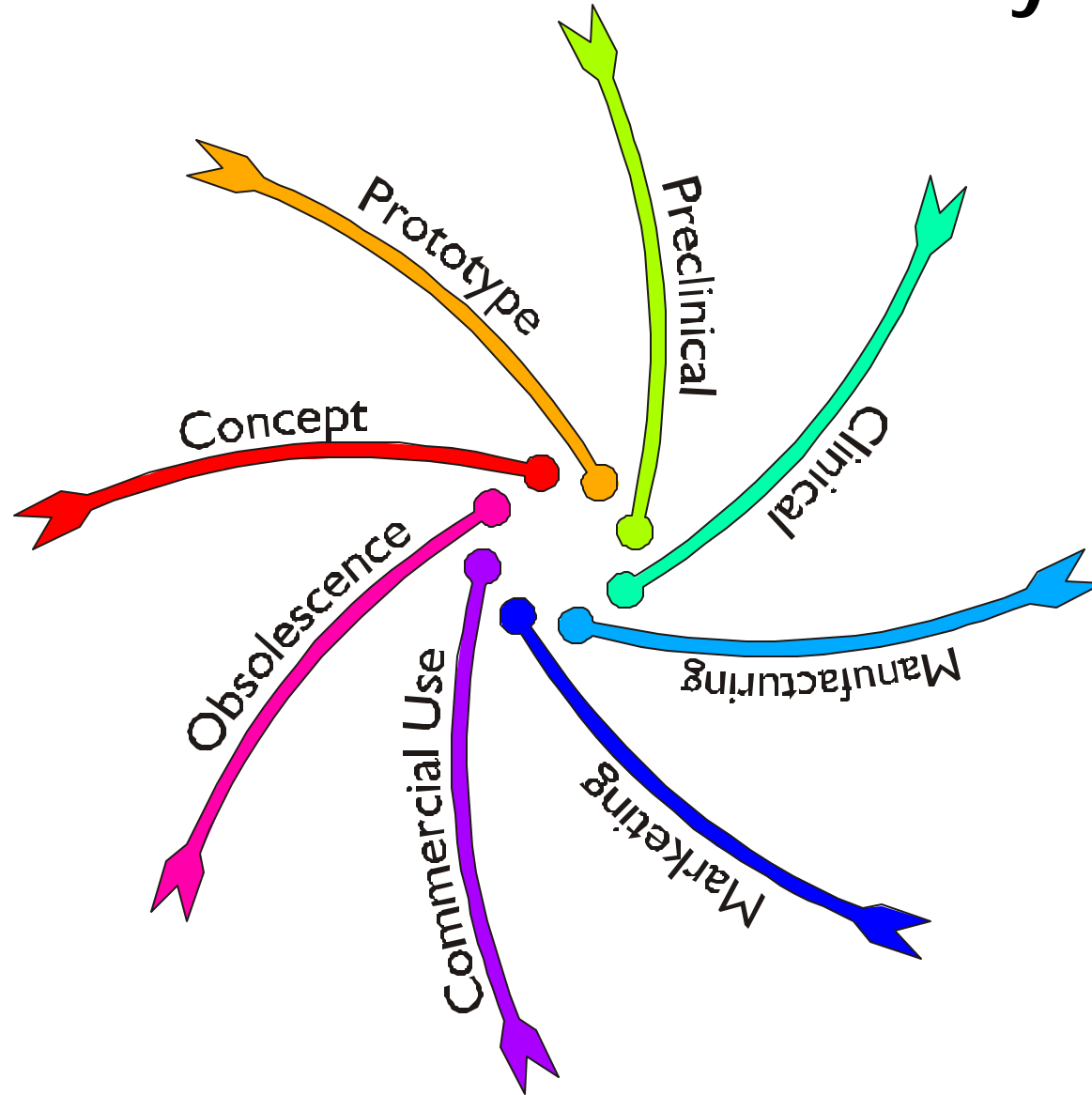
Center for Devices and Radiological Health

Vision:

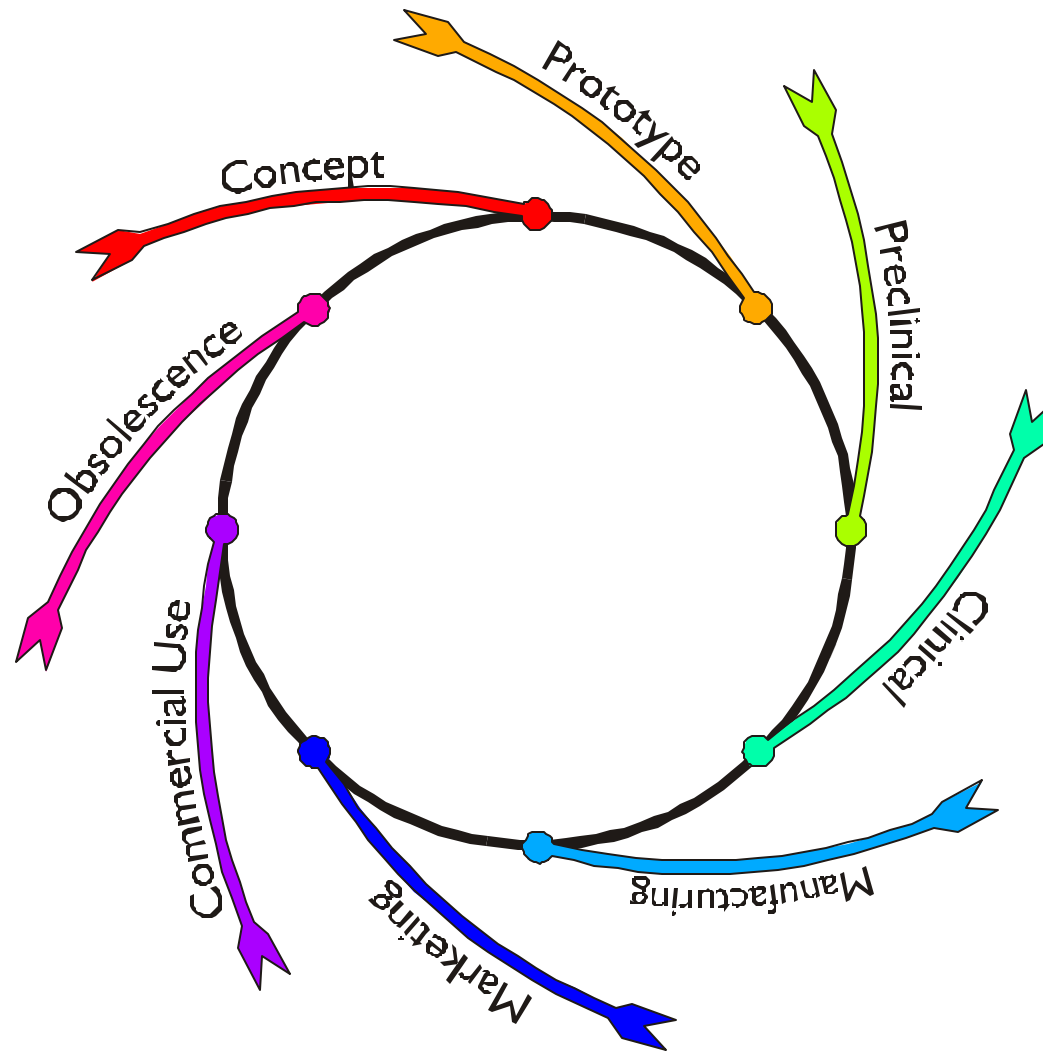
*Ensuring the health of the public
throughout the
Total Product Life Cycle
— it's everybody's business*



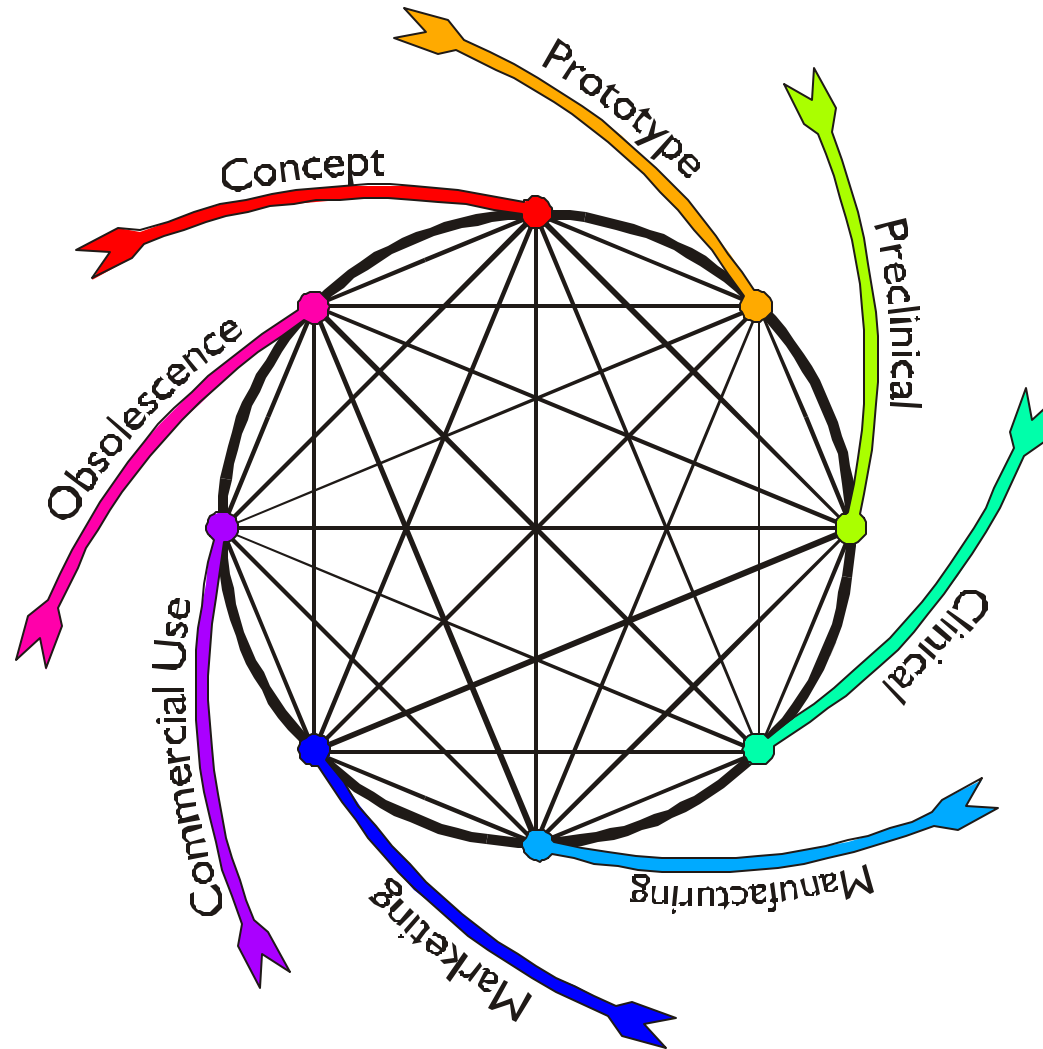
CDRH Vision - Total Product Life Cycle



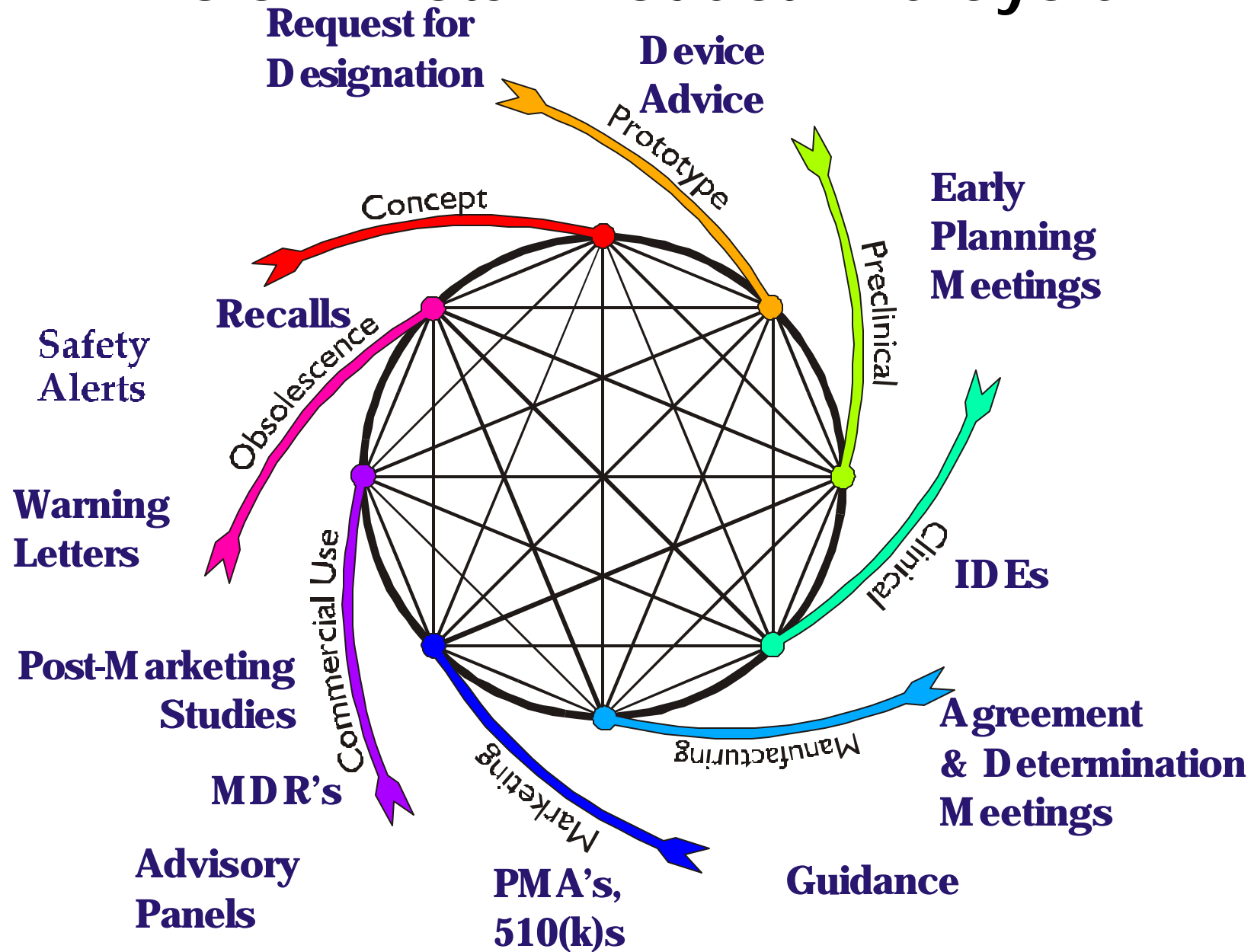
CDRH Vision - Total Product Life Cycle



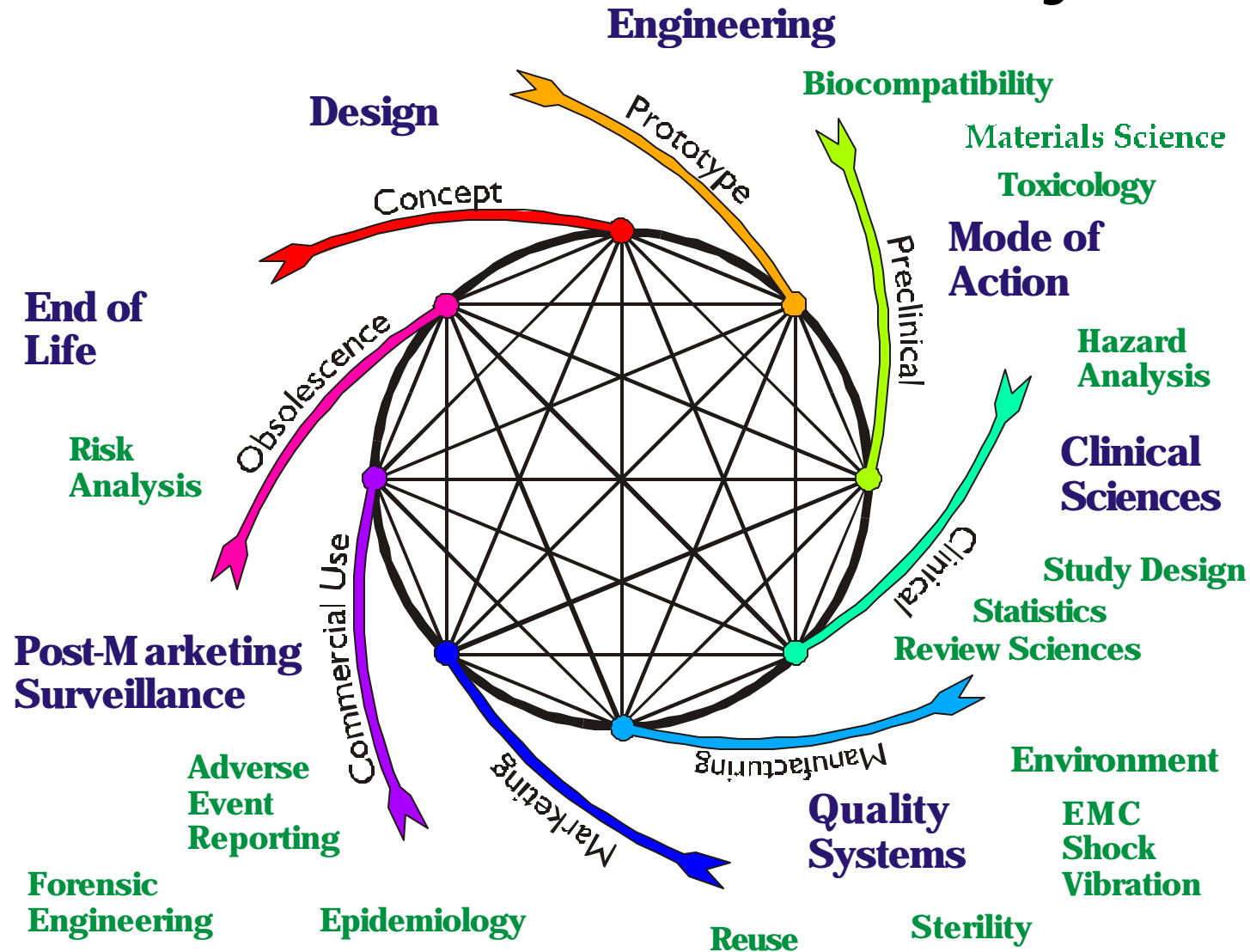
CDRH Vision - Total Product Life Cycle



CDRH Vision - Total Product Life Cycle



CDRH Vision - Total Product Life Cycle



Vision: Ensuring public health throughout the total product life cycle is everybody's business

Underlying Assumptions

- Covering products from concept to obsolescence
- Connected global public health community
- Stakeholders are our partners
- Science fuels the regulatory engine
- Meeting all statutory responsibilities
- Meeting our own standards for quality

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Center for Devices and Radiological Health

Strategic Goals

- *Total Product Life Cycle*
- *Magnet for Excellence*
- *Knowledge Management*
- *Meaningful Metrics*

Strategic Goal: Total Product Life Cycle

To apply the Total Product Life Cycle approach across the range of Center activities

- Develop the TPLC model in coordination with stakeholders:
 - ❖ Internal
 - ❖ External
 - ❖ International
- Implement

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Strategic Goal: Total Product Life Cycle

Areas of Focus

- Eliminate gaps in coverage of TPLC
- Cover statutory responsibilities across the TPLC
- Manage knowledge to support TPLC
- Educate and inform as well as enforce
- Align science-based decision making with TPLC
- Create organizational incentives to support TPLC
- Develop a flexible cross-trained work force to implement TPLC

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Strategic Goal: Total Product Life Cycle

Paradigm Shifts



- | | |
|----------------------|-----------------|
| ➤ Depth | Breadth |
| ➤ Compartmentalized | Seamless |
| ➤ Discrete Processes | Integrated work |
| ➤ High Priority Only | All Mandates |

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Strategic Goal: Magnet for Excellence

To attract and retain a diverse workforce who want to help us fulfill our public health mission

- Be the employer of 1st choice
- Provide opportunity to succeed
- Better link mission and performance

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Strategic Goal: Magnet for Excellence

Paradigm Shifts



➤ Expert (Depth)

Master (Breadth)

➤ Authority

Knowledge
Manager

➤ Institutional Knowledge

Cross Pollination

➤ Narrow Focus

Flexible Focus

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Strategic Goal: Knowledge Management

To manage knowledge to support
TPLC

- Build a knowledge culture
- Exploit Information Technology
- Make CDRH an eCenter

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Strategic Goal: Knowledge Management

Areas of Focus

- Regulatory Science
- Decision Management
- Expertise Systems
- Reference Systems
- Information Technology
- Training Programs

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Strategic Goal: Knowledge Management

Paradigm Shifts



- Information Technology Knowledge Management
- Paperless Office Knowledge Systems
- Self Contained leveraged Knowledge Resources

Strategic Goal: Meaningful Metrics

To measure and set targets to
assess our continuing impact on
public health

- Develop and apply metrics to measure:
 - ❖ The Center's direct and indirect impact on the public health
 - ❖ The effectiveness of the Center's communications
 - ❖ The effectiveness of TPLC implementation

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Strategic Goal: Meaningful Metrics

Measure Impact

- Develop measures of public health impact by CDRH actions that promote product availability, safety and integrity
- Inform stakeholders of performance across the TPLC
- Refine measures of resource use to identify gaps and prioritize efforts to improve performance

Strategic Goal: Meaningful Metrics

Report Cards

- Paradigm – Sample so that information is representative of the whole
- Advantages
 - Trending over time
 - Framework to explore emerging issues
 - A method to have a presence in all our statutory responsibilities
 - More robust to fluctuating resources
 - Can be a force for change

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Strategic Goal: Meaningful Metrics

Paradigm Shifts



➤ Queue

Sampling

➤ Process

Outcome

➤ Review Cycle

Benchmark
ourselves

➤ One by One

Report Cards
to our
Stakeholders

Center for Devices and Radiological Health

Next Steps:

- Center Managers
 - Clarify and refine strategies
 - Develop action plans
- Center Staff
 - Clarify and refine strategies
 - Enlist in implementation teams
- Stakeholders
 - Assure that we will maintain and improve performance
 - Enlist to make TPLC everyone's business